REMARKS

In response to the non-final Office Action mailed February 5, 2008, a response was filed August 4, 2008. The U.S. Patent and Trademark Office ("Office") issued a communication November 18, 2008 stating the response was incomplete for failing to respond to every rejection. This response is responsive to this communication. By this response, claims 1–5 and 7–27 are pending in the application and submitted for reconsideration.

No new matter has been added by this Amendment. Support for the foregoing claim amendments and additions can be found in the specification as-filed, by way of example and not limitation, in the as-filed claims and in Example 1 at pages 16-17.

Rejections Under 35 U.S.C. § 112, 2nd Paragraph

The Office Action has rejected Claims 1, 2, 4–6, 8–12, 15, and 20 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter.

The Office Action rejects Claims 1 and 20 for containing limitations allegedly lacking antecedent basis. Applicants have amended Claim 1 and 20 to clarify the antecedent basis, and thus request that these rejections be withdrawn.

The Office Action has rejected Claims 1, 2, 4–6, 8–12, and 15 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically, the Office Action states "[a] broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite...." The Office Action also alleges that Claims 1, 2, 4-6, 8-12, and 15 are indefinite because they "recite a broad limitation and also recite an additional limitation which is the narrower statement of the limitation" and/or because they "recite a broad range and also recite an additional limitation which is the narrower statement of the range." Applicants have cancelled Claim 6 and have amended Claims 1, 2, 4–5, 8–12 and 15 to clarify the invention, and thus request that these rejections be withdrawn.

In view of the amendments, Applicants respectfully request that all of the rejections under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Office Action has rejected (a) Claims 1–2, 5–12, and 17–19 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,902,513 ("Carvais") in view of U.S. Patent No. 6,699,506 ("Paillard"); (b) Claim 1–4 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Carvais in view of U.S. PGPub No. 2003/0099711 ("Meadows"); and (c) Claims 1–2, 13–16 and 20 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Carvais in view of U.S. PGPub No. 2002/0197327 ("Ulrich").

In levying an obviousness rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing that the prior art references teach or suggests all the claim limitations. *See* M.P.E.P. §§ 2142, 2143. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. . . . [W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007). (citing *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976)). In addition, the Supreme Court has pointed out the "import[ance of] identify[ing] a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the new invention does." *KSR* at 1741. Here, the Examiner has not met the burden of demonstrating that the pending claims are obvious.

Applicants respectfully submit that the Office Action has failed to present a prima facie showing of obviousness, and that none of the pending claims are unpatentable over any of the cited references, either singly or in combination. Accordingly, Applicants request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

35 USC § 103(a) Rejection Over Carvais In View Of Paillard

The Office Action has rejected (a) Claims 1–2, 5–12, and 17–19 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,902,513 ("Carvais") in view of U.S. Patent No. 6,699,506 ("Paillard").

Applicants submit that the combination of Carvais with Paillard neither teaches nor suggests all elements of the claimed invention.

First, neither Carvais nor Paillard teaches the instantly claimed percentages of (i) at least one film-forming polymer (P1) insoluble in the gastrointestinal tract fluids, present in the amount of 50 to 90% by dry weight, based on the total weight of the coating composition, or (ii) at least one surfactant and/or lubricant present in the amount of 2 to 20% by dry weight, based on the total weight of the coating composition. In fact, the Office Action has not even pointed out where, if at all, Carvais and Paillard disclose the claimed percentage. Thus, because the combination of Carvais and Paillard to not teach every element of the claims, Applicants submit the claims are not rendered obvious.

Second, Applicants submit the Office failed to meet their burden for obviousness because the elements of these references do not "perform the same function it had been known to perform" and one of ordinary skill in the art would not have recognized the results of the combination were predictable. MPEP 2143; *KSR* at 1395 – 66. Thus, it's important to identify a reason that would have prompted one of ordinary skill in the art to combine the references in the way the claimed new invention does. *Id.*

Carvais is directed to a "suspension comprising microcapsules of … drug suspended in a saturated solution of said drug, the saturated level of said drug being maintained over a prolonged period of time for sustained release to the bloodstream…" Carvais at col. 1, ll. 30 – 34. Carvais does not teach any type of microcapsule with a coating. Further, Carvais teaches that it is the saturated aqueous solution that controls the sustained release to the bloodstream.

Paillard is directed to dry microgranules comprising an active microsphere containing Milnacipran. Paillard neither teaches nor suggests suspending the microgranules in an aqueous solution at any time before the microgranules are administered to a patient.

One or ordinary skill in the art would not have combined these references to form the instant claims because the reference elements do not perform the same function. For instance, Carvais teaches that the saturated aqueous solution has the function of controlling drug release to the blood stream. In Paillard, the coating is to control release of the drug from a core.

As stated in the instant specification, the liquid suspension is difficult to produce because the amoxicillin is released during storage of the suspension. *See*, specification at page 3, lines 20 – 28. The saturated liquid suspension has the function of prolonging storage of amoxicillin. *Id.* This function was not recognized in Paillard or in Carvais. Further, one of ordinary skill in the art would not combine the aqueous solutions of Carvais, which controls drug release, with the film coating of Paillard, which controls drug release, to obtain a compound where the aqueous solution prolongs drug life during storage by preventing the drug from being released from the microcapsules. As such, Applicants submit that the elements of these two references do not perform the same function as in the instant claims.

For at least these reasons, Applicants submit that independent Claim 1 is patentable over Carvais in combination with Paillard. Each of dependent Claims 2–5 and 7–27 depends directly or indirectly from independent Claim 1, and each adds further patentable features to the patentable features of independent Claim 1. Applicants submit that Claims 1–5 and 7–27 are patentable over Carvais in combination with Paillard and respectfully request that this rejection be withdrawn.

35 USC § 103(a) Rejection Over Carvais In View Of Meadows

The Office Action has rejected Claim 1–4 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Carvais in view of U.S. PGPub No. 2003/0099711 ("Meadows"), allegedly because "it would have been obvious to one of skill in that art at the time the invention was made to use the coating scheme as well as the particle composition of Meadows et al. to produce the sustained release theophylline suspension taught by Carvais." (Office Action at 6–7). Applicants respectfully disagree.

Meadows is directed to active principle bound to small particles of an ion-exchange resin, where the drug-resin complexes are then coated. (*See*, Meadows abstract). The structures of Meadows only work with a very narrow range of active principles because of the charge required. Ion-exchange resins are "ionic or capable of being ionized" and whether the resins can bind with an active principle depends upon the charge of the active principle and the method of binding. Thus, one with skill in the art would recognize that it would not be desirable to use the ion-exchange resins of Meadows to create drug formulations, because the formulations would be narrowly limited as to the type of active principle that may be used. In contrast, the instant

invention may be used with any type of drug, and the charge of the active principle does not matter.

Further, the particles of Meadows do not have the same characteristics as the microcapsules of the instant invention. Indeed, Meadows teaches away from making the microcapsules of the instant invention. Meadows teaches that the coat weight and coat thickness vary the drug release time. Meadows teaches that for drug release within 1–4 hours, the complex should be coated "with a light coat… of about 10% to about 20% by weight of the dry resin," 6 – 10 hours is 30% to 35% by weight of dry resin, and 12 hours is 40 to 50% by weight of dry resin. (*See*, Meadows at paragraph 44).

The teachings of Meadows are in contrast to the instant invention for several reasons. First, the instant invention does not teach use of a dry resin core. Second, the drug release of the instant invention is not dependent upon the percent coat to core by weight. For instance, Example 1 has 700g of a core with 37.6g coat, thus the coat is 5.1% of the microcapsule by weight, but 50% of the drug release does not occur until about 4 hours. Example 3 has a core of 740g, a coat of 265.2g, thus the coat is 26% of the microcapsule by weight, but 50% of the drug release does not occur until about 3 hours.

Moreover, the combination of Carvais and Meadows does not teach all elements of the claims. For instance, neither reference teaches the instantly claimed percentages of: at least one film-forming polymer (P1) insoluble in the gastrointestinal tract fluids, present in the amount of 50 to 90% by dry weight, based on the total weight of the coating composition. Meadows teaches that a polymer should be present in an amount of 44 – 47.5%, preferably from 45 – 46.5%. (*See*, Meadows at paragraph 40). Thus, Meadows teaches away from using polymers in the percentages required by the instant claims.

Further, neither reference teaches the use of at least one nitrogen-containing polymer (P2) present in an amount of 2 to 25% by dry weight, based on the total weight of the coating composition, as is required by the instant claims. In Meadows, the only time a nitrogen-containing polymer (P2) is used, it is as a solvating agent used to impregnate the drug-resin particles. (*See*, Meadows at paragraph 37).

In addition, neither reference teaches the use of at least one surfactant and/or lubricant present in the amount of 2 to 20% by dry weight, based on the total weight of the coating composition, as is required by the instant claims.

For at least these reasons, Applicants submit that independent Claim 1 is patentable over Carvais in combination with Meadows. Each of dependent Claims 2–5 and 7–27 depends directly or indirectly from independent Claim 1, and each adds further patentable features to the patentable features of independent Claim 1. Applicants submits that Claims 1–5 and 7–27 are patentable over Carvais in combination with Meadows and respectfully request that this rejection be withdrawn.

35 USC § 103(a) Rejection Over Carvais In View Of Ulrich

The Office Action has rejected Claims 1–2, 13–16 and 20 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Carvais in view of U.S. PGPub No. 2002/0197327 ("Ulrich").

The combination of Carvais and Ulrich does not teach all elements of the claims. Neither Carvais nor Ulrich teach the combination of (i) at least one film-forming polymer (P1) insoluble in the gastrointestinal tract fluids, present in the amount of 50 to 90% by dry weight, based on the total weight of the coating composition; (ii) at least one nitrogen-containing polymer (P2) present in an amount of 2 to 25% by dry weight, based on the total weight of the coating composition; (iii) at least one plasticizer present in an amount of 2 to 20% by dry weight, based on the total weight of the coating composition; and (iv) at least one surfactant and/or lubricant present in the amount of 2 to 20% by dry weight, based on the total weight of the coating composition, all of which are required by the instant claims.

For at least these reasons, Applicants submit that independent Claim 1 is patentable over Carvais in combination with Ulrich. Each of dependent Claims 2–5 and 7–27 depends directly or indirectly from independent Claim 1, and each adds further patentable features to the patentable features of independent Claim 1. Applicants submit that Claims 1–5 and 7–27 are patentable over Carvais in combination with Ulrich and respectfully request that this rejection be withdrawn.

Conclusion Regarding 35 USC § 103(a) Rejections

Overall, whether taken individually or in combination, Carvais, Paillard, Meadows, and Ulrich fail to teach or suggest each limitation of independent Claim 1. Therefore, Claim 1 is not made obvious by these references. Each of dependent Claims 2–5 and 7–27 depends directly or indirectly from independent Claim 1, and each adds further patentable features to the patentable features of independent Claim 1. Applicants submits that Claims 1–5 and 7–27 are patentable over Carvais, Paillard, Meadows, and Ulrich and respectfully request that the rejections under 35 USC § 103(a) be withdrawn.

DOUBLE PATENTING REJECTIONS

The Office Action also provisionally rejects various claims for nonstatutory obviousness-type double patenting over various applications by themselves or in view of Carvais. Applicants note that each rejection is provisional by procedure, and also notes that the applications used in the provisional rejections are pending.

The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985). The determination of obviousness is a legal conclusion based on underlying factual considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). These factual inquiries include:

1. the scope and content of the prior art;
2. the differences between the prior art and claims at issue;
3. the level of ordinary skill in the pertinent art; and
4. objective evidence of nonobviousness (*i.e.*, secondary considerations).

Graham, 383 U.S. at 17; *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124 (Fed. Cir. 2000). The "determination of obviousness 'does not require absolute predictability of success . . . . [A]ll that is required is a reasonable expectation of success.'" *Brown & Williamson Tobacco Corp.*, 229 F.3d at 1125 (*quoting, In re O'Farrell*, 853 F.2d 894, 903-904 (Fed. Cir. 1988)).

In levying an obviousness rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing that the prior art references teach or suggests all the claim limitations. *See* M.P.E.P. §§ 2142, 2143. The Supreme Court has also pointed out the "import[ance of] identify[ing] a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007). Here, the Examiner has not met the burden of demonstrating that the pending claims are obvious.

Nonstatutory obvious-type double patenting rejection over U.S. Ser. No. 10/522,252 in view of Carvais

The Office rejected claims 1 – 2, 4 – 10, 15 and 17 provisionally on grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 – 17 and 19 – 31 of copending U.S. Ser. No. 10/522,252 ("'252 application") in view of Carvais.

The Office states the combination would be obvious because the '252 application teaches microcapsules comprising a film forming polymer insoluble in the gastrointenstinal tract fluid, a water soluble polymer and a plasticizer. Office Action at 8. Further, both the instant application and the '252 application teaches the microcapsules being present within the suspension at a level between 5 and 70% and presence of a solubilizing agent in a liquid phase. *Id.* at 8 – 9. The Office relies on Carvais to provide the limitation of a liquid phase of a suspension saturated with amoxicillin.

Applicants assert the claims would not be obvious because one of ordinary skill in the art would not have combined the elements as claimed by known methods such that each element merely performs the same function as it did separately, while recognizing that the results of the combination were predictable.

The '252 application is to microcapsules for "prolonged release of active principles with low solubility." The '252 application at abstract. The need or problem addressed by this application is to prepare microcapsules with a film coating that have a sustained release. Claims 16 – 17 and 19 – 31 of the '252 application do not include use of a solution or suspension. Further, the '252 application does not provide a disclosure regarding the microparticles being in a suspension at a level between 5 and 70%. The only disclosure which comes close is the

examples of the '252 application, where a microcapsule comprising 5.3% of a medium solution. *See, Id.* at Examples 1 – 3. When placed in aqueous solution, however, the microcapsules release 50% of their drug in 4 – 6 hours, and 100% of their drug between 12 and 24 hours. Further, when uncoated, the granules release more than 97% in one hour. *See, Id.* at paragraph 172. This runs counter to the instant invention, which is designed so that when the claimed microcapsules are in a liquid suspension the modified release of the amoxicillin according to a profile that **does not change**. See, instant application at Abstract.

Carvais is directed to a "suspension comprising microcapsules of ... drug suspended in a saturated solution of said drug, the saturated level of said drug being maintained over a prolonged period of time for sustained release to the bloodstream..." Carvais at col. 1, ll. 30 – 34. Thus, it is the saturated aqueous solution that controls the sustained release to the bloodstream. In fact, Carvais does not teach any type of microcapsule with a coating.

One of ordinary skill in the art would not have combined these references to form the instant claims because the reference elements do not perform the same function. For instance, Carvais teaches that the saturated aqueous solution has the function of controlling drug release to the blood stream. In the '252 application, the coating is to control release of the drug from a core when the microcapsule is placed in a liquid solution.

As stated in the instant specification, the liquid suspension is difficult to produce because the amoxicillin is released during storage of the suspension. *See*, specification at page 3, lines 20 – 28. The saturated liquid suspension has the function of prolonging storage of amoxicillin. *Id.* This function was not recognized in the '252 application or in Carvais. Further, one of ordinary skill in the art would not combine the aqueous solutions of Carvais, which controls drug release, with the film coating of the '252 application, which controls drug release, to obtain a compound where the aqueous solution prolongs drug life during storage by preventing the drug from being released from the microcapsules. As such, Applicants submit that the elements of these two references do not perform the same function as in the instant claims.

Nonstatutory obvious-type double patenting rejection over U.S. Ser. No. 10/492,129 in view of Carvais

The Office rejected claims 1 – 3, 5 – 10 and 17 – 19 provisionally on grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 4, 7 – 8 and 11 – 12 of copending U.S. Ser. No. 10/492,129 ("'129 application") in view of Carvais.

Specifically, the Examiner alleges that it would be obvious to combine the references because the '129 application teaches oral compositions comprising hydrophilic polymer carrying groups that are ionized at neural pH and a hydrophobic polymer and Carvais teaches use of a liquid phase suspension. Office Action at 9. Applicants respectfully disagree.

The instant claims require at least one film-forming polymer (P1) insoluble in gastrointestinal tract fluids comprising a water-insoluble cellulose derivative present in the amount of 50 – 90% by dry weight; at least one nitrogen-containing polymer (P2) selected from the group consisting of polyacrylamide, poly-N-vinylamide, and poly-N-vinyllactam, present in the amount of 2 – 25% by dry weight; and at least one plasticizer selected from the group consisting of: glycerol esters, phthalates, citrates, sebacates, cetyl alcohol esters, and castor oil and present in the amount of 2 – 20% by dry weight. *See*, as amended claim 1.

Neither Carvais nor the '129 application teach all three of these elements in their claimed ratios.

Nonstatutory obvious-type double patenting rejection over U.S. Ser. No. 11/707,034 in view of Carvais

The Office rejected claims 1 – 3, 5 – 10, 17 and 19 provisionally on grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 9, 11 – 24, 26, 31, 41 – 50, 58 – 76, 89 – 91, 99 – 101 and 113 of copending U.S. Ser. No. 11/707,034 ("'034 application") in view of Carvais.

The Office states the combination would be obvious because the '034 application teaches use of a film with the same three compositions. Office Action at 10. The Office relies on Carvais to provide the limitation of a liquid phase of a suspension saturated with drug. *Id.*

Applicants assert the claims would not be obvious because one of ordinary skill in the art would not have combined the elements as claimed by known methods such that each element merely performs the same function as it did separately, while recognizing that the results of the combination were predictable.

The '034 application is to compositions, including reservoir, matrix type, gastric retentive or multiparticulate form. '034 application at Abstract. The need or problem addressed by this application is to prepare ribavirin for sustained release formulations that increase the bio-absorption of ribavirin. Id. at ¶19. The '034 application does not provide a disclosure regarding the microparticles being in a suspension at a level between 5 and 70%. Indeed, the only examples use capsules or tablets placed in solution, not microcapsules placed in solution. Further, even when microcapsules are placed in a capsule or tablet, which is placed in solution, the microcapsule are not between 5 and 70% of a suspension. *See, Id.*. at Examples 1 – 3. When placed in aqueous solution, the *tablets* and *capsules* (which contain microcapsules) release 50% of their drug in 1 – 6 hours, and 80 – 100% of their drug between 8 and 16 hours. *See, Id.* at Figure 1. This runs counter to the instant invention, which is designed so that when the claimed microcapsules are in a liquid suspension the modified release of the drug according to a profile that **does not change**. See, instant application at Abstract.

Carvais is directed to a "suspension comprising microcapsules of … drug suspended in a saturated solution of said drug, the saturated level of said drug being maintained over a prolonged period of time for sustained release to the bloodstream…" Carvais at col. 1, ll. 30 – 34. Thus, it is the saturated aqueous solution that controls the sustained release to the bloodstream. In fact, Carvais does not teach any type of microcapsule with a coating.

One of ordinary skill in the art would not have combined these references to form the instant claims because the reference elements do not perform the same function. For instance, Carvais teaches that the saturated aqueous solution has the function of controlling drug release to the blood stream once the drug is administered to the individual. In the '034 application, the coating is to control release of the drug from a core when the microcapsule it orally administered to an individual.

As stated in the instant specification, the liquid suspension is difficult to produce because the amoxicillin is released during storage of the suspension. *See*, specification at page 3, lines 20 – 28. The saturated liquid suspension has the function of prolonging storage of amoxicillin. *Id.* This function was not recognized in the '252 application or in Carvais. Further, one of ordinary skill in the art would not combine the aqueous solutions of Carvais, which controls drug release, with the film coating of the '252 application, which controls drug release, to obtain a compound where the aqueous solution prolongs drug life during storage by preventing the drug from being released from the microcapsules. As such, Applicants submit that the elements of these two references do not perform the same function as in the instant claims.

Nonstatutory obvious-type double patenting rejection over various references

The Office alleged on page 9 – 10 of the Office Action that fifteen copending applications contain subject matter which is "strikingly similar to those used here against instant application" and in view of Carvais "most if not all of these applications would result in provisional rejections." Further, the Examiner states it is "incumbent upon the application to delineate the differences between the claimed subject matter and the copending claims in view of the Carvais or file terminal disclaimers." Office Action at 10. The Examiner did not state which claims are rejected.

Applicants respectfully disagree. The MPEP states that to make an obviousness rejection,

> [T]he examiner should set forth in the Office action:
>
> (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
>
> (B) the difference or differences in the claim over the applied reference(s),
>
> (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and

> (D) an explanation as to why the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made.
>
> "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 97" (Bd. Pat. App. & Inter. 1985).

MPEP 706.02(j).

The Examiner has not set forth the differences between the instant claims and these references. The Examiner also did not explain why one of ordinary skill in the art would have found the instant claims obvious. Further, Applicants note that MPEP 706.02(j) teaches that the burden is on the Examiner to show why the instant claims are rendered obvious. Thus, Applicants disagree that it is "incumbent upon the applicant to delineate the differences" between the claimed invention and other references.

Further, the Examiner did not cite which claims are provisionally rejected. Without further guidance from the Examiner, the Applicant is currently unable to respond to this rejection.

CONCLUSION

Applicant believes the application is now in condition for allowance. Reconsideration and withdrawal of the rejections are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned below.

Applicants submit concurrently a request for a one-month extension of time under 37 C.F.R. 1.136 and the accompanying fee. Please charge our Credit Card in the amount of $130.00, covering the fee set forth in 37 CFR 1.136(a). In the event that any additional extension of time is necessary to prevent the abandonment of this patent application, then such extension of time is petitioned. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-2228, from which the undersigned is authorized to draw, under Order No. 022290.0120PTUS.

Dated: December 19, 2008

Respectfully submitted,

By_____

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